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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/518,723

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Nicolaas Duneas

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EXAMINER

KEMMERER, ELIZABETH

ART UNIT

PAPER NUMBER

1646

MAIL DATE

DELIVERY MODE

04/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,723	Applicant(s) DUNEAS, NICOLAAS	
	Examiner Elizabeth C. Kemmerer, Ph.D.	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-50 is/are pending in the application.
- 4a) Of the above claim(s) 37-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/23/06, 8/27/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (claim 36) in the reply filed on 21 February 2008 is acknowledged.

Claims 37-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 21 February 2008.

Status of Application, Amendments, And/Or Claims

The preliminary amendments of 20 December 2004, 23 February 2006, and 21 February 2008 have been entered in full. Claims 1-35 are canceled, claims 37-50 are withdrawn from consideration as discussed above, and claim 36 is under examination.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: METHOD OF PREPARING AN OSTEOGENIC PROTEIN FRACTION.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over either of Scott et al. (1994, The Anatomical Record 238:23-30) or Yoshimura et al. (1993, Biol. Pharm. Bull. 16:444-447) in view of Kuberasampath et al. (U.S. Patent 4,968,590; issued 06 November 1990).

At p. 24, 3rd through 5th paragraphs of left column, Scott et al. teach a method of preparing an osteogenic protein fraction comprising extracting demineralized bone matrix with a solution of a guanidium salt (Gu-HCl), removing high molecular weight proteins exceeding 300 kDa by ultrafiltration (using Millicon Pellicon system which first excludes proteins over 100 kDa [including proteins over 300 kDa]), subjecting the lower molecular weight fraction to heparin affinity chromatography, and exchanging the purified osteogenic protein fraction into a solvent appropriate for human medical use (deionized H₂O).

Similarly, Yoshimura et al. teach a method of preparing an osteogenic protein fraction comprising extracting demineralized bone matrix with a solution of a guanidium salt (Gnd.HCl), removing high molecular weight proteins exceeding 300 kDa by ultrafiltration (using Minitan ultrafiltration system which excludes proteins over 100 kDa [including proteins over 300 kDa]), subjecting the lower molecular weight fraction to heparin affinity chromatography, and exchanging the purified osteogenic protein fraction

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into a solvent appropriate for human medical use (telopeptide-free type I collagen using alcohol precipitation). See p. 444-445, Materials and Methods section.

Neither Scott et al. nor Yoshimura et al. teach an additional purification step of hydroxyapatite chromatography. However, such was well known in the art at the time of the invention.

For example, Kuberasampath et al. teach the additional step of hydroxyapatite chromatography after heparin affinity chromatography. See col. 6-7.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to add the hydroxyapatite chromatography step of Kuberasampath et al. after the purification steps of either of Scott et al. or Yoshimura et al. with a reasonable expectation of success, as such was the result of combining prior art elements according to known methods to yield predictable results.

Thus, the invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ECK

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646